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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
RAE, CHARLESWORTH E	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/566,253
Filing Date: January 30, 2006
Appellant(s): SAEKI ET AL.

Harris Pitlick
Registration NO. 38,779
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 25, 2008 appealing from the Office action mailed May 1, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief contains a statement concerning related appeals or interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

This appeal involves claims 1-4 and 29-34.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. Rejection of Claim 34 under 102(b) over Ohkuchi et al. (US 6,348,468) is withdrawn. Rejection of claims 1-4 and 29-32 on the provisional ground of nonstatutory obviousness-type double patenting over claims 7-9 of copending application No. 11/574,319 is withdrawn.

CORRECTED REJECTIONS

Appellant's Ground (A) and Ground (B) statements of the grounds of rejection regarding the rejections under 102(b) and 103(a) are incorrect.

With respect to Ground (A), it is noted that Appellant incorrectly stated the ground of rejection of claims 1-4 and 29-34 under 35 U.S.C. 102(b) as anticipated by US 6,348,468 (Ohkuchi et al.) in view of WO 00/63241 (Ashkar et al.). However, claims 1-4 and 29-33 stand rejected under 102(b) as anticipated by US 6,348,468 (Ohkuchi et al.). WO 00/63241 to Askar et al is only relied upon as an evidentiary reference. As noted above, the rejection of claim 34 is withdrawn.

With respect to Ground (B), appellant incorrectly stated the ground of rejection of claim 34 as rejected under 103(a) as unpatentable over Ohkuchi et al. in view of Ashkar et al. and McPhaden et al, *Plasma Osteopontin Levels in Multiple Myeloma, Blood, J. American Society of Hematology*, 1994;84(10, Suppl 1), page 172a, abstract 674. However, claim 34 is rejected under 103(a) as unpatentable over Ohkuchi et al., in view of McPhaden et al, *Plasma Osteopontin Levels in Multiple Myeloma, Blood, J. American Society of Hematology*, 1994;84(10, Suppl 1), page 172a, abstract 674 only. WO 00/63241 to Askar et al is only relied upon as an evidentiary reference.

CURRENT REJECTIONS

(1) Ground A should read: Claims 1-4 and 29-33 under 35 U.S.C. 102(b) as anticipated by US 6,348,468 (Ohkuchi et al.) .

(2) Ground B should read: Claim 34 is rejected under 103(a) as unpatentable over Ohkuchi et al. in view McPhaden et al, *Plasma Osteopontin Levels in Multiple Myeloma, Blood, J. American Society of Hematology*, 1994;84(10, Suppl 1), page 172a, abstract 674.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6348468	Ohkuchi et al.	02-2002
WO 00/6324	Ashkar et al.	10-2000

Blood, J. American Society of Hematology, McPhaden et al., November, 1994: 84(10, Suppl 1): 172a, abstract #674, Plasma osteopontin levels in multiple myeloma.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections – 35 USC -102(b)

(A) Claims 1-4 and 29-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohkuchi et al. (6,348,468).

Ohkuchi et al. teach pyridazine derivative compounds, including applicant's elected compound species, 2-benzyl-5-(4-chlorophenyl)-6-[4-(methylthio)phenyl]-2H-pyridazin-3-one, and methods of treatment comprising administering said compounds (see Example 132; col. 54). Ohkuchi et al. teach a pharmaceutical composition comprising said pyridazine derivative compounds or *salt thereof* in combination with a pharmaceutically acceptable carrier (col. 3, lines 1-4). Ohkuchi et al. teach said compounds are effective ingredients when administered orally or parenterally to an adult in an amount of about 0.01 to 1,000 mg per day, wherein said amount is effective to inhibit interleukin-1 beta(IL-1 beta) in a mammal (col. 13, lines 39-45; and reference

claim 7). Ohkuchi et al. teach methods of treating ischemic nephritis comprising administering said compounds (col. 13, lines 10-23).

It is noted that the term "administering to a subject in need thereof of an effective amount of a pyridazine compound of formula I" as recited in claim 1 is construed to be an active method step which is satisfied by the teaching of Ohkuchi et al. of a therapeutically effective amount of appellant's elected compound.

To the extent that Ohkuchi et al. teach the same compounds to treat the same patient population (patients with kidney disease, e.g. ischemic nephritis) as the instant application, the preamble of claims 1 and 29 are inherent.

Ashkar et al. (WO 00/63241) is added as an evidentiary reference only to show that kidney disease (i.e. glomerulonephritis) and arthritis are modulated by osteopontin (OPN). One would reasonably expect that administration of a therapeutically effective amount of a compound in a dose of 0.01 to 1,000 mg per day to inhibit IL-1 beta in an adult (= subject) with ischemic nephritis as taught by Ohkuchi et al. would also be effective to inhibit OPN production in said mammal because ischemic nephritis is a kidney disease and kidney diseases are modulated by OPN.

Claims Rejections – 35 USC – 103(a)

(B) Claim 34 is rejected under U.S.C. 103(a) as being unpatentable over Ohkuchi et al. (6,348,468), in view of McPhaden et al. (McPhaden et al, Plasma

Osteopontin Levels in Multiple Myeloma, Blood, J. American Society of Hematology, 1994;84(10, Suppl 1), page 172a, abstract 674).

The above discussion of Ohkuchi et al. is incorporated by reference. Although Ohkuchi et al. teach a method of treating IL-1 beta related conditions, Ohkuchi et al. do not teach multiple myeloma.

McPhaden et al. teach multiple myeloma (abstract). McPhaden et al. also teach that osteopontin appears to be important in bone metabolism and may be a clinical marker of osteoblast and/or osteoclast activity in multiple myeloma (abstract). Also, McPhaden et al. teach that a number of osteoclast activating factors have been implicated in multiple myeloma, including interleukin-1/3 (= IL-1 beta).

It would have been obvious to a person of skill in the art at the time the invention was made to combine the teachings of the above references to treat multiple myeloma as taught by McPhaden et al. with the method of treatment comprising administering a compound in a therapeutically effective amount as taught by Ohkuchi et al. (e.g. applicant's elected compound) to treat multiple myeloma. One would have been motivated to treat multiple myeloma in because McPhaden suggest that IL-1 beta is an osteoclastic activating factor that is implicated in multiple myeloma and Ohkuchi et al. teach the instant compounds are effective in treating IL-1 beta related conditions (e.g. ischemic nephritis). Further, one would reasonably have expected that a therapeutically effective amount of a compound (e.g. applicant's elected compound) used to treat ischemic nephritis, wherein said condition is associated with IL-1 beta, as taught by

Ohkuchi et al., would also be effective in inhibiting the production of OPN because osteopontin is a clinical marker for osteoclastic activating factors, including IL-1 beta, such that a decrease in IL-1 beta activity would be accompanied by a decrease in osteopontin.

(10) Response to Argument

(A) Claims 1-4 and 29-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohkuchi et al. (6,348,468).

The rejection under 102(b) is maintained with respect to claims 1-4, and 29-33 as appellant's arguments are not found to be persuasive for the reasons previously made of record.

Appellant argued that the rejection is improper because the examiner failed to recite Ashkar et al. in the ground of rejection heading in the Office action, mailed 05/01/08, even though the examiner relied upon the reference. Appellant stated that "where a reference is relied on to support a rejection, whether or not in a "minor capacity," there would appear to be no excuse for not positively including the reference in the statement of rejection." In re Hoch, 428 F.2d 1341, 166 USPQ 406, 407 n.3 (CCPA 1970). MPEP 706.02(j).

This argument is not found to be persuasive since Ashkar et al. is not being relied upon to establish anticipation but is only cited as an evidentiary reference in support of the examiner's position of inherency. In fact, in the Office action mailed 09/12/07, the examiner clearly established inherency based solely on Ohkuchi et al.

Again, it is the examiner's position that since Ohkuchi et al. disclose the same compounds to treat the same patient population (patients with kidney disease, e.g. ischemic nephritis) the preamble is inherent. Thus, the claims are anticipated over Ohkuchi et al itself. In the subsequent Office action, however, the examiner merely relied on Ashkar et al. as an evidentiary reference to support the basis for inherency. Accordingly, the examiner properly communicated the basis of the rejection and the appellant was given fair opportunity to reply. (MPEP 706.02(j). Thus, it is the examiner's position that the rejection under 102(b) is proper.

Appellant argued that the examiner has failed to show a nexus between IL-1 beta and OPN production and that ischemic nephritis has not been shown to be associated with enhanced OPN production.

This argument is not found to be persuasive since the term "a kidney disease" is anticipated by the Ohkuchi's disclosure of ischemic nephritis Thus, Ohkuchi administers the instant compounds to the same patient population (patients with kidney disease, e.g. ischemic nephritis) and therefore the preamble would inherently occur. Although Ohkuchi does not explicitly disclose inhibiting the production of OPN, Ohkuchi discloses the same method steps. Thus, it is respectfully submitted that : "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily

make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Further, one would reasonably expect that treatment of a subject with a “nephritis" kidney disease (e.g. ischemic nephritis) with a therapeutically effective amount of the instant compound disclosed by Ohkuchi et al. would necessarily inhibit the production OPN in said subject as evidenced by the teaching of Ashkar et al. that glomerulonephritis is modulated by osteopontin. The examiner hereby points out that appellant’s assertion that it has not been shown that ischemic nephritis is associated with enhanced OPN production is inconsistent with the instant application wherein it is expressly stated that “OPN production is known to be increased in kidney disease.” See specification, page 2, para. 0003. Thus, the teaching of ischemic nephritis by Ohkuchi et al. provides a nexus between IL-1 beta and osteopontin as evidenced by Ashkar et al.

Appellant further argued that the term “a kidney disease" is limited to only the members recited in the Markush group, which precludes conditions that do not result from enhanced OPN production.

This argument is not found to be persuasive since the limitation “a kidney disease” as recited in claim 33 encompasses ischemic nephritis by Ohkuchi et al.. Thus, the broad limitation “kidney disease” is anticipated by the disclosure of ischemic nephritis .Thus, administering the instant compound taught by Ohkuchi et al. (e.g. applicant’s elected compound species) to an adult (= subject) with ischemic nephritis would necessarily exhibit the same treatment effects; i.e. inhibiting OPN production since the same drug is administered to the same population. Further, the therapeutically effective dose of 0.01 to 1,000 mg of the compounds taught by Ohkuchi et al. is

identical to the dose disclosed in the instant application as being therapeutically effective to inhibit OPN production and/or effective to treat conditions associated with enhanced OPN production (see specification, page 2, para. 0003; and pages 14-15, para. 0031).

Appellant also argued that the term "to a subject in need thereof of an effective amount of a pyridazine derivative …" limits the instant population to only subjects in need of treatment to inhibit OPN production and that the patient population encompassed by Ohkuchi et al. is not so limited.

This argument is not found to be persuasive since the prior art discloses the same population, i.e. patients suffering from kidney disease. It is further pointed out that "kidney disease" is one of the Markush species in claim 33 that results "in enhanced OPN production" as claimed. Thus, the patient in need of thereof is any patient with the disease of claim 33 and Ohkuchi et al. teach a kidney disease (i.e. ischemic nephritis).

In addition, appellant argued that Ohkuchi et al. do not disclose or suggest methods of using the claimed compounds to treat diseases implicated by OPN production.

This argument is not found to be persuasive since as stated previously Ohkuchi et al. discloses the same method steps wherein appellant's elected compound is administered therapeutically effective amount (0.01 to 1,000 mg) for use in methods of treating ischemic nephritis (= a kidney disease). Kidney diseases are known to be associated with enhanced/increased OPN production as discussed above. Again the examiner respectfully submitted that : "[T]he discovery of a previously unappreciated

property of a prior art composition, or ofa scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

To the extent that the Ohkuchi et al. teach the same instantly claimed compound to treat the same population (kidney disease e.g. nephritis), the instant claim limitations are anticipated by the cited art.

(B) Claim 34 is rejected under U.S.C. 103(a) as being unpatentable over Ohkuchi et al. (6,348,468), in view of McPhaden et al. (McPhaden et al, Plasma Osteopontin Levels in Multiple Myeloma, Blood, J. American Society of Hematology, 1994;84(10, Suppl 1), page 172a, abstract 674).

In response, appellant argued that Ohkuchi et al. is deficient for the reasons delineated in appellant's response to the rejection under 102(b). The examiner's response to applicant's arguments in connection with the rejection under 102(b) (i.e. Grounds A) is incorporated by reference.

It is noted that appellant's discussion regarding Ashkar et al. is irrelevant to the rejection under 103(a) because Ashkar et al is only relied upon on as an evidentiary reference to bolster the examiner's position and the reference is not used to anticipate the claims.

Appellant argued that McPhaden et al. do not cure the deficiency of Ohkuchi et al. because McPhaden et al. does not disclose any connection or nexus between inhibiting interleukin-1 beta production, as taught by Ohkuchi et al., and inhibiting OPN production. Instead, McPhaden et al. simply discloses a connection between OPN production and multiple myeloma.

This argument is not found persuasive because McPhaden et al. suggest that osteopontin is a clinical marker of osteoblast and/or osteoclast activity in multiple myeloma and that osteoclastic activating factors, including IL-1 beta, are also implicated in multiple myeloma and Ohkuchi et al. teach the instant compounds inhibit IL-1 beta. Thus, since McPhaden et al. teaches that IL-1 beta is implicated in myeloma, one would reasonably expect that treatment of a subject with multiple myeloma as taught by McPhaden et al. with a therapeutically effective amount of a compound taught by Ohkuchi et al. (an IL-1 beta inhibitor), wherein said therapeutically effective amount is effective to inhibit IL-1 beta, would also be effective to inhibit OPN production in said subject with multiple myeloma. Thus, the preamble is implicit since the combination of references teach the same compounds administered to the same population (i.e. multiple myeloma).

Thus, it would have been obvious to a person of skill in the art at the time the invention was made to create the instant claimed invention with reasonable predictability.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Respectfully submitted,

/Charlesworth Rae/

Examiner, Art Unit 1611

Conferees:

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612